

### Remarks

This amendment is responsive to the U.S. Patent and Trademark Office Action mailed February 12, 2002. Entry of the Amendment is believed to be in order as placing the case in condition for allowance or in better form for appeal. Pursuant to 37 C.F.R. § 1.116, reconsideration of the present application in view of the foregoing amendments and the following remarks is respectfully requested.

Applicants' attorney thanks the Examiner for his comments. Applicants' attorney also notes the Examiner's statement that Claim 18 is objected to, but would be allowable if rewritten in independent form. In light of the above amendments to Claims 1, 11, 15 and 18, it is the Applicants' contention that not only are Claims 1, 11, 15, and 18 allowable as amended, but so too are each of the remaining claims which depend therefrom.

### Double Patenting Rejections

By way of the Office Action mailed February 12, 2002, it is believed that the is attempting to make a double patenting rejection. However, as the rejection is not clear, due to the multiple citations of the same claims in the rejection, the Applicants are unable to appropriately address the rejection. Due to the uncertainty of the rejection the Applicants respectfully submit that if the Examiner will clarify the rejection, the Applicants will respond accordingly.

### Rejections under 35 U.S.C. § 102

By way of the Office Actions mailed June 6, 2001 and February 12, 2002, the Examiner rejected Claims 1, 11 and 15 under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,490,503 of Hollister (hereinafter "Hollister" or "the '503 patent"). The Examiner contends Hollister "discloses and apparatus comprising a suction catheter 1 configured for removing fluids from a respiratory tract of a patient having a distal end configured for suctioning secretions from the respiratory system of a patient; a protective sleeve 2 surrounding a proximal longitudinal portion of the catheter; a manifold 4 defining a ventilation circuit disposed in communication with the catheter to be advanced through the ventilation circuit of the manifold and into the respiratory tract of the patient; and a valve 70 disposed in the manifold, the valve being configured to selectively limit the withdrawal of air from the ventilation circuit and for at least partially occluding the distal end of the catheter, the valve being able to frictionally engage the distal end (col. 2, lines 1-45), wherein the valve comprises at least one protrusion 82, 84 on at least one surface of the valve." In Paragraph 2 of the most recent Office Action, the Examiner

suggests "that as best seen in Fig. 4, the valve of Hollister does have protrusions as best illustrated by the reference numbers 82, 84, and 92. Furthermore, Hollister discloses the use of duckbill valves, which inherently have protrusions represented by the duckbill."

As stated in the Applicants' previous response, to establish anticipation under 102(b), the cited reference must teach each and every element or step of the rejected claim. As stated in Applicants' original reply, Hollister does not disclose at least one protrusion on at least one surface of the valve. While Hollister does disclose a novel wiper assembly and one way valve assembly 70, none of the valves 82 to 85 of the assembly 70 have a protrusion on the surface of the valve. The Examiner suggests that a duckbill valve inherently has at least one protrusion on the surface of the valve. Applicants suggest that the Examiner does not appreciate the Applicants' point nor the description of the valves.

First, Applicants' respectfully submit that the Examiner has misinterpreted the disclosure of the Hollister reference and in so doing has mischaracterized the teachings in his Office Action. That is, the Examiner referred on numerous occasions in his Office Action (as well as during a telephone call with Applicants' Attorney for clarification of the rejections) to valve 70. It is submitted that the Hollister reference clearly sets forth that reference numeral 70 is a valve assembly and not a valve. Hollister clearly identifies that the reference numeral used therein to identify valves are 82-85. Because of the numerous references throughout Hollister which clearly refer to valve assembly 70 and valves 82-85 it is Applicants' position that the Examiner is incorrect in basing his rejection on the assembly rather than the valve itself. It is Applicants' position that for the Examiner to ignore (and, in fact, to take a position contrary to) the teachings and suggestions of the Hollister reference is not only incorrect, but also improper under the patent laws of the United States. That is, more specifically, the valves in Hollister have clearly been defined as 82-85, and to suggest that the valve is something other than what has been expressly defined is improper as the Examiner has provided no support for his proposed expanded definition. Accordingly, Applicants suggest that if the Examiner were to examine the Hollister reference in light of its teachings and suggestions, it is clear that the valves 82-85 and valve assembly 70 are not one and the same. It is further suggested that after the mischaracterization is clarified, that an examination of the valves 82-85 reveals that the valves comprise a sleeve 90 of oval shape open at its proximal end, left-hand end and closed at its distal, right-hand end by two converging lips 92 and 94." (Column 4, lines 39-42) This citation further suggests

the Examiner has misinterpreted the reference, especially when viewed in light of Paragraph 2 of the Office Action, where the Examiner contends 82, 84 and 92 are protrusions. Again 82 and 84 are clearly defined as valves and as such cannot be protrusions on the valves. Further 92 is a lip which is part of valve 82, but there is no teaching or suggestion of a protrusion from lip 92. As such it was and is the Applicants' position and contention that the claims were allowable prior to the amendments submitted herewith.

Notwithstanding the above discussion, the Applicants submit that the above amendments remove the basis for the Examiner's rejection. More specifically, Applicants' contend that there is nothing in the disclosure of the '503 patent which teaches or suggests each of the limitations of Claims 1, 11 and 15 as amended. The remaining claims in the present application are similarly distinguishable not only because of the patentability of the independent claims but also because of the combination of the subject matter of each of the dependent claims with their independent claim which makes each claim further distinguishable, and which is not taught or suggested by the cited references, singly or in combination.

As the Hollister patent fails to teach or suggest each of the limitations in the claims of the present invention, as amended, the Hollister reference must fail as a reference under 35 U.S.C. §§102(b). Accordingly, it is respectfully submitted that the Examiner's rejection should be withdrawn.

By way of the Office Action mailed February 12, 2002, the Examiner also rejected Claims 2, 5, 7-10, 12, 16 and 17 under 35 U.S.C. §103(a), as being unpatentable over Hollister in view of U.S. Patent No. 5,582,161 of Kee (hereinafter "Kee" or "the '161 patent"). Again, as noted above, Claims 2, 5, 7-10, 12, 16 and 17 depend either directly or indirectly from Claims 1, 11 or 15 and recite the present invention in varying scope. As discussed above the Hollister patent fails to teach or suggest each and every element which is present in the amended claims of the present invention, and Kee fails to provide a teaching or suggestion of the elements which Hollister fails to teach or suggest. Where the cited references fail to teach or suggest each of the claimed elements to one skilled in the art, the rejection must fail.

Again, as the Applicants have herein discussed the cited references in relation to claims 1, 11 and 15. Claims 2, 5, 7-10, 12, 16 and 17 are similarly distinguishable not only because of the patentability of the independent claims but also because of the combination of the subject matter of each of the dependent claims with their independent


claim which makes each claim further distinguishable, and which is not taught or suggested by the cited references, singly or in combination. Accordingly, it is respectfully submitted that the Examiner's rejection of Claims 2, 5, 7-10, 12, 16 and 17 should be withdrawn.

Applicants have carefully reviewed the art cited against the present application and amended the claims to even more clearly and patentably distinguish such claims over such art. None of the cited references, either alone or in combination, discloses a composite construction which has the same or similar distinctive combination of features as set forth and claimed in the newly amended claims and it is this combination of elements which is clearly and patentably distinguishable over the cited art. All claims, as now amended, are believed to be patentably distinguishable over the cited references and in allowable condition. Applicants respectfully request the rejections of the claims under 35 U.S.C. §§ 102 and 103 be reconsidered and withdrawn in light of the preceding amendments and remarks.

For the foregoing reasons, the application and claims are believed to be in condition for allowance and such action is respectfully requested. However, should any questions arise with regard to this matter the Examiner is encouraged to contact the undersigned at (770)-587-7183. Please charge any prosecutorial fees which are due to Kimberly-Clark Worldwide, Inc. deposit account number 11-0875.


Respectfully submitted,

Chet M. Crump et al.

By:   
William W. Letson  
Registration No.: 42,797  
Attorney for Applicants

#### CERTIFICATE OF MAILING

I, William W. Letson, hereby certify that on June 12, 2002 this document is being deposited with the United States Postal Service as first-class mail, postage prepaid, in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

By:   
William W. Letson

**Claims:**

**1. (Amended.) An apparatus comprising:**

a catheter configured for receiving fluids from a respiratory tract of a patient;  
a manifold defining a ventilation circuit disposed in communication with the catheter so as to allow the catheter to be advanced through the ventilation circuit of the manifold and into the respiratory tract of the patient; and  
a valve disposed in the manifold, the valve being configured to selectively limit the withdrawal of air from the ventilation circuit, wherein the valve comprises at least one protrusion on at least one surface of the valve, and wherein the valve is a flap.

**11. (Amended.) An endotracheal catheter system comprising:**

a catheter having a distal end configured for suctioning secretions from the respiratory system of a patient;  
a ventilator manifold disposed in communication with the catheter such that the catheter may be advanced through the manifold into the respiratory system of the patient and withdrawn from the respiratory system of the patient through the manifold; and  
a valve for at least partially occluding the distal end of the catheter, the valve being configured to frictionally engage the distal end and thereby occlude the distal end wherein the valve comprises a flap and wherein the valve further comprises at least one protrusion on at least one surface of the valve.

**15. (Twice Amended.) A respiratory suction apparatus comprising:**

a suction catheter having a distal end for suctioning secretions;  
a protective sleeve surrounding a proximal longitudinal portion of the catheter;  
a manifold connected to the protective sleeve for attachment to a hub of an artificial airway in fluid communication between the respiratory tract of a patient and a ventilator, said manifold having means for accommodating inspiration and expiration of respiratory gases; and  
a valve connected to the manifold and pivotally moveable with respect thereto for engaging the distal end of the catheter to minimize the amount of air being drawn thereinto responsive to suction through the catheter wherein the valve comprises a flap and wherein the valve further comprises at least one protrusion on a surface of the valve.

18. (Twice Amended.) A respiratory suction apparatus comprising:

- a suction catheter having a distal end for suctioning secretions;
- a protective sleeve surrounding a proximal longitudinal portion of the catheter;
- a manifold connected to the protective sleeve for attachment to a hub of an artificial airway in fluid communication between the respiratory tract of a patient and a ventilator, said manifold having means for accommodating inspiration and expiration of respiratory gases; [and]

- a valve connected to the manifold and pivotally moveable with respect thereto for engaging the distal end of the catheter to minimize the amount of air being drawn thereinto responsive to suction through the catheter wherein the valve comprises at least one protrusion on a surface of the valve; wherein the valve comprises a pivotable flap disposed to selectively separate the distal end of the catheter; and

- a means for enhancing the turbulence of the air.